# Alvotech Initiates Patient Study for AVT06, a Proposed Biosimilar for Eylea®

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- *AVT06 is the third biosimilar candidate developed by Alvotech to enter clinical studies*
- *Eylea® (aflibercept) is used for the treatment of eye disorders and reached global sales of nearly US$10 billion in 2021*
- *The patient study is expected to enroll approximately 444 participants globally*

REYKJAVIK, Iceland, July 07, 2022 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today the initiation of the company's confirmatory clinical study for AVT06 (aflibercept), a biosimilar candidate to Eylea®. The objective of the study is to compare AVT06 and Eylea® in terms of efficacy, safety, and immunogenicity in adult patients with neovascular (wet) age-related macular degeneration (AMD).

The study (ALVOEYE) is a randomized, double-masked, parallel-group, multicenter, therapeutic equivalence study, and is expected to enroll approximately 444 participants globally. The study's primary endpoint is the change in best corrected visual acuity (BVCA) from baseline to week 8.

Eylea® (aflibercept) is a widely used biologic for the treatment of a variety of eye disorders including ones which can lead to vision loss or blindness, such as wet AMD, macular edema, and diabetic retinopathy. In 2021, world-wide sales of Eylea® were nearly US$10 billion[1].

"We are delighted at the sustained progress of our product pipeline as we continue to leverage our integrated development and manufacturing platform and execute our global biosimilar strategy," said Robert Wessman, Founder and Executive Chairman.

Joseph McClellan, Chief Scientific Officer, added: "The initiation of this patient study marks an important step in the development of our AVT06 biosimilar candidate, and demonstrates Alvotech's commitment to developing biosimilars addressing key therapeutic areas in order to improve the lives of people around the world."

Alvotech's current portfolio of eight products and product candidates target treating autoimmune disease, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech's lead product, AVT02 (adalimumab), a biosimilar to Humira ®, the world's highest grossing medicine (excluding COVID-19 vaccines), has already been approved and launched in Canada and Europe and is expected to launch in the United States on July 1, 2023[2]. Alvotech has also announced positive topline results for AVT04 (ustekinumab), a proposed biosimilar to Stelara®, from both a confirmatory clinical, safety and efficacy study and a pharmacokinetic (PK) study.

[1]EVALUATE Pharma
[2]Subject to regulatory approval

**About AVT06 (aflibercept)**

AVT06 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept). Aflibercept binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability. AVT06 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

**About AVT02 (adalimumab)**

AVT02 is a monoclonal antibody and a biosimilar to Humira® (adalimumab), which inhibits tumor necrosis factor alpha (TNF-alpha). AVT02 is not approved outside of the EU, Norway, Iceland, Lichtenstein, the UK, Switzerland, and Canada. AVT02 dossiers are under review in multiple countries; in the U.S. the initial BLA for approval as a biosimilar is in deferred status, pending the result of FDA inspections.

**About AVT04 (ustekinumab)**

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara® (ustekinumab). Ustekinumab binds to two cytokines called interleukin-12 and interleukin-23 that are involved in inflammatory and immune responses. Abnormal regulation of these cytokines has been associated with immune mediated diseases, such as psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. AVT04 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

**About Alvotech**

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline contains eight biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU and select other territories), Fuji Pharma Co., Ltd (Japan), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and

territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

**Forward-Looking Statements**

Certain statements in this communication may be considered "forward-looking statements." Forward-looking statements generally relate to future events or the future financial operating performance of Alvotech. For example, Alvotech's expectations regarding capitalization through equity or debt financing, future growth, results of operations, performance, future capital and other expenditures including the development of critical infrastructure for the global healthcare markets, competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, expected patient enrollment, the potential approval and commercial launch of its product candidates and the timing of the announcement of clinical study results, regulatory approvals and market launches, and the estimated size of the total addressable market of Alvotech's pipeline products. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech, with Alvotech as the surviving company (the "Business Combination"); (2) the ability to maintain stock exchange listing standards; (3) the risk that the Business Combination disrupts current plans and operations of Alvotech; (4) the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition, the ability of the Alvotech to grow and manage growth profitably, maintain key relationships and retain its management and key employees; (5) changes in applicable laws or regulations; (6) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (7) Alvotech's estimates of expenses and profitability; (8) Alvotech's ability to develop, manufacture and commercialize the product candidates in its pipeline; (9) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (12) The ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its product candidates, including the timing or likelihood of expansion into additional markets or geographies; (14) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (15) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (16) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (18) the potential impact of the ongoing COVID-19 pandemic on the FDA's review timelines, including its ability to complete timely inspection of manufacturing sites; and (16) other risks and uncertainties set forth in the section entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in Alvotech's Registration Statement on Form F-4 or in other documents filed with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. 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